K100883

5. 510(k) Summary

DEC 2 1 2010

Submitter: ETEX Corporation
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Date Prepared: March 19, 2010

Product Code(s): LYC (21 CFR 872.3930)

Device Class: II (21 CFR 872.3930)

Classification Panel: Dental Devices

Classification Name: Bone Grafting Material, Synthetic (21 CFR 872.3930)

Proprietary Name: CarriGen Porous Bone Substitute Material

Predicate Device(s): Alpha-bsm Bone Substitute Material (ETEX Corp., K091729)
Beta-bsm Injectable Bone Substitute Material (ETEX Corp., K091729)
Gamma-bsm Moldable Bone Substitute Material (ETEX Corp., K091729)
EquivaBone Osteoinductive Bone Graft Substitute (ETEX Corp., K091729)

Device Description: CarriGen Porous Bone Substitute Material is a synthetic, biocompatible bone graft substitute material. At the time of use, the powder component is combined with a specified volume of mixing solution and mixed to form a putty. The resulting putty is administered to the treatment site by manual application. The material can be shaped into a desired form *in-situ* prior to implantation. After the putty is applied to the treatment site, it hardens at body temperature and converts to an apatitic calcium phosphate material. The end product, nano-crystalline hydroxyapatite

(NCHA), is of low crystalline order with a similar chemical and crystalline structure to that of natural bone minerals. Gamma-bsm Moldable Bone Substitute Material is an osteoconductive material that is resorbed and replaced by natural bone over time.

Intended Use: CarriGen Porous Bone Substitute is an injectable, self setting, macro-porous, osteo-conductive, calcium phosphate bone graft substitute material that is intended to be used in bony voids or gaps to fill and/or augment dental intraosseous, intraoral and maxillofacial defects. These defects include periodontal/infrabony defects; alveolar ridge augmentation (sinusotomy, osteotomy, apicoectomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation / placement); sinus lifts; cystic defects; and oral and maxillofacial augmentation. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. CarriGen is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Materials: Synthetic calcium phosphate, sodium carboxymethyl cellulose and EfferSoda (a commercial formulation of 88% sodium bicarbonate and 12% sodium carbonate)

Performance Data: Testing data meeting the requirements of *Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices* (dated April 28, 2005) has been submitted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Christopher Klaczyk
Regulatory Affairs Manager
Etex Corporation
38 Sidney Street
Cambridge, Massachusetts 02139

DEC 21 2010

Re: K100883
Trade/Device Name: CarriGen Porous Bone Substitute Material
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: December 7, 2010
Received: December 8, 2010

Dear Mr. Klaczyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

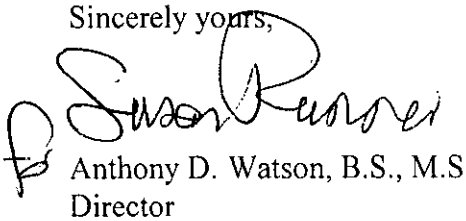
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications For Use

510(k) Number (if known):

Device Name: CarriGen Porous Bone Substitute Material

Indications for Use:

CarriGen Porous Bone Substitute is an injectable, self setting, macro-porous, osteo-conductive, calcium phosphate bone graft substitute material that is intended to be used in bony voids or gaps to fill and/or augment dental intraosseous, intraoral and maxillofacial defects. These defects include periodontal/infrabony defects; alveolar ridge augmentation (sinusotomy, osteotomy, apicoectomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation / placement); sinus lifts; cystic defects; and oral and maxillofacial augmentation. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. CarriGen is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K100883